510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K061064

B. Purpose for Submission:

Addition of Quality Control Levels for linearity

C. Measurand:

White Blood Cells (WBC), Red Blood Cells (RBC), Hemoglobin (Hgb), Platelets (Plt)

D. Type of Test:

Quantitative

E. Applicant:

Beckman Coulter, Inc.

F. Proprietary and Established Names:

COULTER® LIN-C Linearity Control

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.8625, Hematology quality control mixture

2. Classification:

   Class II

3. Product code:

   JPK, Mixture, Hematology Quality Control

4. Panel:

   Hematology (81)

H. Intended Use:

1. Intended use(s):

   COULTER® LIN-C linearity controls are intended to verify the reportable range of COULTER hematology analyzer listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents. Refer to Manuals or On-line Help System.

2. Indication(s) for use:

   COULTER® LIN-C linearity controls are intended to verify the reportable range of COULTER hematology analyzer listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents. Refer to Manuals or On-line Help System.

3. Special conditions for use statement(s):

   Extended levels (0, 6 through 10) of the COULTER® LIN-C linearity controls are to be used on the COULTER® LH 750 and COULTER® LH 780 hematology analyzers only.

4. Special instrument requirements:

   Not applicable.

I. Device Description:

COULTER® LIN-C linearity controls are stabilized human blood components from which repeated measurements are made to verify the reportable range for Beckman Coulter hematology systems. The controls are supplied in a kit containing 3.3 mL vials of Levels 0-10.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   COULTER® Linearity Control

2. Predicate 510(k) number(s):

   K955334

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	COULTER® LIN-C	COULTER® Linearity Control (K955334)
Intended Use	COULTER LIN-C linearity controls are intended to verify the reportable range of COULTER hematology analyzer listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents. Refer to Manuals or On-line Help System.	Same
Product Contents	Consists of treated stabilized human and fixed animal erythrocytes, a stabilized platelet-sized component, and fixed erythrocytes to simulate leukocytes.	Same
Assayed Parameters	WBC, RBC, HGB, PLT	Same
Open Vial Stability	7 days when stored at 2-8^{o} C	Same
Closed Vial Stability	120 days when stored at 2-8^{o} C	Same

Differences		
Item	Device	Predicate
Levels of control	0-10	1-5
Analyzers	COULTER LH 750, LH 780	COULTER LH 750, LH 500, GenS, HmX, MaxM, MaxM A/L, Onyx, Act Series, Act Diff, Act Diff 2, MD, MD II, T Series, JT, JT2/3, STKS
Ranges Covered	WBC: 0-400 x 10^3 RBC: 0-8.0 x 10^8 HGB: 0-25 PLT: 0-3000 x 10^3	WBC: 0-100 x 10^3 RBC: 0-7.5 x 10^8 HGB: 0-20 PLT: 0-1000 x 10^3

K. Standard/Guidance Document Referenced (if applicable):

No applicable.

L. Test Principle:

COULTER® LIN-C linearity controls are made to verify the reportable range of Beckman Coulter hematology systems. To ensure the accuracy of linearity control ranges, Beckman Coulter systems are calibrated with S-CAL calibrator and maintained according to the appropriate Product Manual or Online Help System.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Not Applicable.

   b. Linearity/assay reportable range:

   Not Applicable.

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):

   Closed vial stability was performed using 20 lots of the additional levels of LIN-C Linearity Control. These lots were tested 3 times per month. Six aspirations per level from one new closed vial were performed at each test point (12-120 days).

   Open vial stability was performed using 20 lots of the additional levels of LIN-C Linearity Control. These lots were tested monthly. Two vials per level were evaluated at each time point (12-120 days). A single aspiration was performed on Day 1 to initiate the open vial condition followed by six aspirations on Day 7 to validate open vial claim of 7 days.

   Assigned Values for Levels 6-9 are confirmed by multiple analysis of the control product. For Level 0, since it does not contain any cellular components, a fixed acceptable recovery range (low and high limits) was developed by Beckman Coulter which will be applied and verified on each lot manufactured.

   d. Detection limit:

   Not Applicable.

   e. Analytical specificity:

   Not Applicable.

f. Assay cut-off:

Not Applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not Applicable.

b. Matrix comparison:

Not Applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable.

b. Clinical specificity:

Not Applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable.

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

Expected ranges were calculated by Beckman Coulter based on data collected on validated systems using specific Beckman Coulter reagents and are included with each kit. Mean values should recover within the ranges. The ranges established by Beckman Coulter should be used as a guideline. Each laboratory must establish its own criteria for acceptable results.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.